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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,039	12/22/2005	Yukihiro Ohno	0020-5455PUS1	6314

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EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
03/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,039	OHNO ET AL.	
	Examiner	Art Unit	
	Noble Jarrell	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/05;4/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I in the reply filed on 1/31/2008 is acknowledged.

Priority

2. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country. Applicants do not have priority to PCT/JP04/09095 because it was not published in English. In addition, applicants do not have priority to JP2003-178386, because an English translation was not provided.

Claim Objections

3. Claims 1-6 and 11-12 are objected to because of the following informalities: non-elected subject matter is contained in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants are not enabled for teaching how to use the instantly claimed imide compounds to treatment and or prevention Alzheimer's dementia. Pulley et al, (US 7067507, issued June 27, 2006) show that Alzheimer's disease cannot be treated or prevented (column 2, lines 40-45). In addition, simultaneous

prevention and treatment is not enabled. If a subject does not have a disorder, treatment cannot occur. If a subject already has a disorder, prevention cannot occur.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to treatment and/or prevention of a cognitive dysfunction.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Pulley et al. show that treatment or prevention of Alzheimer's disease is not possible.

(5) The relative skill of those in the art:

One of ordinary skill in the art knows that Alzheimer's disease is not preventable.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification does not provide guidance for any treatment or prevention of Alzheimer's dementia.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to claims 1-12 and the high degree of unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of skill in this art would be burdened with undue experimentation to practice the invention commensurate in the scope with the instant claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3, 5, 7, 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What "cognitive dysfunction" is being treated and/or prevented in the claims? A cognitive dysfunction can be Alzheimer's disease, or can be amnesia or delusion. It is difficult to ascertain the metes and bounds of this term and in the absence of a specifically described or designated dysfunction, the terminology fails to particularly point out the subject matter applicant regards as the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Saji et al. (EP 464846, published January 8, 1992, which corresponds to US 5532372 of the IDS). Saji et al. teach compounds 101 (page 33), 107 (page 34), and 108 (page 35), each of which have valid groups for the elected group. Each of the compounds has nitrogen for variable G, CH_2-

cyclohexyl-CH_2 for variable D, zero for variable N, and C(O) or SO_2 for variable B. In each of these compounds, a combination of variables R^1 and R^3 form a six-membered ring that is fused to the ring with variable B. Other compounds in EP 464846 that anticipate claims 1-12 are compounds 8-13, 17-22, 47-50, 60-61, and 67-72 of table 9. Claims 1-12 are each compound claims, and the intended use carries little to no patentable weight. Thus, the compounds themselves anticipate each of the claims. Claim 9 is directly anticipated by compound 101.

10. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujihara (WO2002024166, published 03/28/2000). Fujihara teaches compound SM-13496 (Registry number 367514-88-3) on page 7, which directly anticipates the compound of claim 9, and is the hydrochloride salt of compound 101 of EP 464846. Claims 1-12 are each compound claims, and the intended use carries little to no patentable weight. Thus, the compounds themselves anticipate each of the claims.

11. Claims 1-8 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Norman et al. (*Journal of Medicinal Chemistry*, **1996**, *39(1)*, 149-157). Norman et al. teach compound 22 (page 150) and its hydrochloride salt (page 154, second column, 2nd preparation). In this compound, D is CH2-cyclopropyl-CH2, G is N, B is C(O), R^1 and R^3 form a phenyl ring. Claims 1-8 and 11-12 are each compound claims, and the intended use carries no patentable weight. Thus, the compounds themselves anticipate each of the claims.

Allowable Subject Matter

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624